

EXHIBIT A

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Premarket Approval (PMA)



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Note: this medical device record is a supplement. The device description may have changed. Be sure to look at the [original PMA](#)²³ to get an up-to-date view of this device.

Trade Name	SYNCHROMED II PROGRAMMABLE DRUG INFUSION SYSTEM
Classification Name	Pump, Infusion, Implanted, Programmable ²⁴
Generic Name	Implantable Infusion Pumps
Applicant	MEDTRONIC VASCULAR
PMA Number	P860004
Supplement Number	S056
Date Received	04/07/2003
Decision Date	09/12/2003
Product Code	LKK [Registered Establishments With LKK ²⁵]
Advisory Committee	General Hospital
Supplement Type	Normal 180 Day Track
Supplement Reason	Change Design/Components/Specifications - Other
Expedited Review Granted?	No

Combination Product No

Recalls

[CDRH Recalls](#)²⁶

Approval Order Statement

Approval for the medtronic synchromed ii programmable drug infusion system which includes model 8637 synchromed ii programmable pump, synchromed ii application software on the model 8870 application card, model 8551 refill kit, model 8540 catheter access port kit, and model 8590-1 pouch kit.

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